

Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed June 10, 2009. Currently, claims 22-38 and 42-47 remain pending of which claims 34-38 were previously withdrawn. The Examiner has apparently provisionally withdrawn claims 43-47, as a restriction requirement involving those claims is pending. Claim 4 appears to have been erroneously listed as pending. Claims 22-33 and 42 have been rejected. Claims 22, 43, 45, and 47 have been amended to clarify the relationships among the elements. Claim 44 has been canceled. No new matter has been introduced. Favorable consideration of the following remarks is respectfully requested.

Election/Restrictions

Applicant believes that the Examiner intended to identify two inventions under 35 U.S.C. 121:

Invention I drawn to a cross-linked gelatin composition comprising a wetting agent which decreases hydration time of the gelatin composition corresponding to claims 22-33 and 42.

Invention II drawn to a delivery system including a cross-linked gelatin composition comprising a wetting agent which decreases hydration time of the gelatin composition corresponding to claims 43-47, claim 44 having been canceled by this communication.

Although the Examiner constructively elected Invention I corresponding to claims 22-33 and 42, Applicant respectfully traverses the restriction requirement and requests reconsideration and withdrawal of the restriction requirement. In the event that the restriction becomes final, Applicant provisionally elects Invention II drawn to a deliver

The Examiner has asserted that claims 43-47 are directed to an invention that is independent or distinct from the invention originally claimed further asserting that claims 43-47 "are directed to composition comprising crosslinked gelatin, wetting agent and saline solution, while instant claim 22 does not require saline solution, rather non-aqueous solvent. Additionally, claims 44-47 require syringe assembly having specific structure that is not required by the composition of claims 22-33, and 42. Invention of

claims 22-34 and 42 and invention of claims 43-47 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects.” In support of this position, the Examiner has indicated a belief that the invention of claims 22-34 and 42 does not require the syringe that is required by the invention of claims 43-47. Applicant believes that the syringe delivery system is necessary to properly utilize the pledget of claim 22 because of the reduced hydration time which results from the presence of the wetting agent. The Examiner further asserts that the composition of claim 22 is distinct from the composition of claim 43 as claim 22 requires non-aqueous solution and claim 43 require aqueous solution. Applicant believes that the Examiner has misread claim 22 as indicating that the pledget of claim 22 is hydrated by a non-aqueous solvent. A non-aqueous solvent would appear to be incapable of “hydrating” the pledget. Claim 22 has been amended to clarify that the wetting agent, which decreases the hydration time of the gelatin sponge, is characterized by being soluble in a non-aqueous solvent. Incorporation of the wetting agent into the gelatin composition of claim 22 is described at page 11, lines 18-27. As described therein, the liquid solvent is removed by evaporation prior to hydration of the gelatin composition in the delivery system of claim 43. Accordingly the conflict assumed by the Examiner does not exist and the composition of claim 22 is the composition used in claim 43 where the enhanced hydration found in claims 22 and 43 is accomplished with an aqueous saline solution within the holding chamber of the syringe. The importance of the syringe/holding chamber of the pledget delivery system is described at page 4, line 8 to page 5, line 8 and page 5, line 25 to page 6, line 10. The system rapidly converts the crosslinked gelatin composition/wetting agent combination into a flowable pledget and delivers the hydrated pledget while retaining the structural integrity of the hydrated pledget.

Thus Applicant respectfully disagrees with the Examiner’s analysis of the claims in question. Claims 22-34 and 42 describe a pledget which has properties which suit it for use with the delivery system of claims 43-47, namely a gelatin pledget comprising a wetting agent “wherein the wetting agent decreases hydration time of the gelatin sponge” and the delivery system provides the protection necessary to create the hydrated sponge and retain its structural integrity during delivery. Claim 43 has been amended and claim

44 has been canceled to clarify this relationship. It is believed that the language of the claims as previously presented may have led to the apparent confusion. The claims in question have been amended to clarify the invention. In conclusion, the crosslinked gelatin sponge with associated wetting agent of pending claims 22-33, 42, 43, and 45-47 are the same. The pledget responds rapidly to hydration, which is further limited to hydration by a saline solution in the delivery system of claim 43. The sponge of claims 22-33 and 42 is the sponge used in the delivery system of claims 43 and 45-47 and the delivery system uses properties of the sponge to an unexpected advantage. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the restriction requirement.

Specification

The Examiner has objected to the amendment to the specification filed January 13, 2009 as introducing new matter. Applicant respectfully traverses the objection. Although this is a positive assertion, the Examiner has not indicated which feature or features of the drawing described by Figure 1 is new, but merely speculates that new matter may have been added “because it is not known if figure 1 is the original assembly applicant invented.” As specified in 35 U.S.C. 113, “The Applicant shall furnish a drawing where necessary for the subject matter sought to be patented.” Drawings submitted after the filing date may not be used to overcome any insufficiency of the specification due to lack of an enabling disclosure or to supplement the original disclosure thereof for the purpose of interpretation of the scope of any claim. Although a drawing does not appear to be required for the sponge of claims 22-33 and 42, it was felt that it could contribute to the understanding of claims 43 and 45-74 by providing a non-limiting illustrative embodiment. As currently presented, Figure 1 is believed to illustrate one of a number of possible embodiments of the delivery system of claims 43 and 45-47, while limiting the presentation of the claimed elements to matter already disclosed in the specification and claims. As such, it is believed to introduce no new matter and Applicant has made no attempt to rely upon any feature which appears solely in the Figure. In the absence of such reliance, there would appear to be no basis for the

objection to the addition of a reference to the figure and the inclusion of reference numerals in paragraph [0053].

Paragraph [0053] originally, and following amendment, made reference to a pledget of crosslinked gelatin composition of the invention as discussed elsewhere in the specification and claims; as well as a syringe assembly comprising a holding chamber, an injection port which comprises a luer hub, an ejection port, and a cannula. No additional matter regarding the particular configuration of the components or their structure is claimed or relied upon. The Examiner has correctly noted that paragraph [0053] does not describe that the sterile saline is added through side tube (12) and that the paragraph does not describe the relation of the parts together to assure that the drawing was original citing that the position of the cannula in relation to the ejection port is not clear from reading paragraph [0053]. Applicant respectfully submits that the amendment would have been improper if it had included specifics of the side tube or the cannula rather than noting their presence. As described and claimed, the invention is not restricted to a particular arrangement of the elements in question, but rather to embodiments in which the elements are present. Accordingly, paragraph [0053], both before and after amendment, describes embodiments of the invention which are equivalent with respect to the elements which are present. The amendment does not appear to introduce any new features not found in the original specification nor does it appear to introduce any feature which has been relied upon in prosecuting the application. Applicant respectfully requests that the objection to the specification be withdrawn.

Claim Rejections – 35 USC § 112

Claims 22-33 and 42 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Although claims 22-33 and 42 are drawn to Invention I and Applicant has provisionally elected Invention II, corresponding to claims 43 and 45-47, subject to a request for reconsideration of the restriction requirement, the §112 rejection will be addressed to advance prosecution. Claims 22-33 and 42 are drawn to a crosslinked gelatin sponge comprising a wetting agent which decreases hydration time of the gelatin sponge. This is amply demonstrated by the examples provided. See Examples 2, 3, and 8 where hydration times were reduced when

the wetting agent was present and the solvent in which the wetting agent is soluble was variously ethanol or isopropanol. Note that the solvent is used during incorporation of the wetting agent and need not be present during the hydration time testing (claim 22) or when the sponge is hydrated and ejected from the delivery system (claim 43). The use of a cannula delivery tube system is disclosed in Example 7.

Possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention.

A specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998). See also *UMC Elecs. Co. v. United States*, 816 F.2d 647, 652, 2 USPQ2d 1465, 1468 (Fed. Cir. 1987) (“[T]here cannot be a reduction to practice of the invention *** without a physical embodiment which includes all limitations of the claim.”); *Estee Lauder Inc. v. L’Oreal, S.A.*, 129 F.3d 588, 593, 44 USPQ2d 1610, 1614 (Fed. Cir. 1997) (MPEP 2163, II., 3., (a).)

Accordingly, Applicant respectfully submits that the matter of claims 22-33 and 42 was present in the application as filed and requests that the rejections be withdrawn.

Claim Rejections – 35 USC § 103

Claims 22-29, 31, and 42 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yasushi et al. (JP 02-182259), hereinafter Yasushi, in view of Song et al. (EP 0 568 334), hereinafter Song. After careful review, Applicant must respectfully traverse this rejection.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03).

Although claims 22-33 and 42 are drawn to Invention I and Applicant has provisionally elected Invention II, corresponding to claims 43 and 45-47, subject to a

request for reconsideration of the restriction requirement, the §103 rejection will be addressed to advance prosecution.

Nowhere does Yasushi appear to disclose “a cross-linked gelatin sponge; and a wetting agent; wherein the wetting agent decreases hydration time of the gelatin sponge”. Instead, Yasushi appears to disclose a gelatin sponge formed by adding a foam stabilizing surfactant to a water swollen mass of gelatin and foaming the resulting mass. The foamed mass was subsequently freeze dried and cross-linked by soaking for 1 hour in ethanol containing gluteraldehyde. In the absence of information regarding the ethanol solubility of the coconut oil collagen peptide potassium salt employed in the sole example which appears to be pertinent, one does not appear to be able to determine if surfactant remains in or on the sponge. Further, Yasushi does not appear to disclose a decreased hydration time of his combination much less a composition in which a wetting agent is known to be present. The only available comparison appears to be to an uncross-linked gelatin.

Although the Examiner has referred to page 6, second full paragraph as disclosing evaporation of solvent, a more careful reading will show that the surfactant is added to an aqueous gelatin solution and no addition/removal of solvent or even drying appears to be disclosed. Similarly, the cited text at page 7, line 3 appears to have been mischaracterized. Yasushi teaches that the amount of cross-linking agent in the cross-linking is preferably 0.0001 – 10.0 mol per gram of gelatin. The cited text refers to the consequence of using less than 0.0001 mol per gram of gelatin and does not appear to make reference to the presence of a wetting agent. Further the passages do not appear to teach or disclose that a cross-linked sponge having an associated wetting agent exhibit decreased hydration times, only that uncross-linked or very lightly cross-linked gelatins are soluble in blood or body fluids.

Further still, although the term “ready for use” does not appear in the claims in question, the Examiner appears rely upon the term as somehow indicative of the state of hydration, but not of hydration time, and appears to have ignored the distinction between the term “ready for use” as it might be applied to the pending application where the term implies that the material is sufficiently hydrated to be expelled from a syringe and the

term as applied to a topical bandage of Yasushi which does not appear to require any hydration prior to application to a wound and so is “ready for use” in a completely non-hydrated state. There appears to be nothing in the disclosure of Yasushi which suggests that hydration is necessary to the function of the topical bandage.

In attempting to characterize the Yasushi reference as applied to the pending claims, the Examiner repeats the earlier misconception that a non-aqueous solvent is present in the composition of claim 22. The reference to a non-aqueous solvent in is the characterization of the wetting agent employed, as clarified in the amended claim 22. Accordingly, there is no requirement that a non-aqueous solvent be present in the claimed composition. That this misconception exists is further confirmed by the Examiner’s assertion that a “One would reasonably expect formulating hemostatic composition comprising cross linked gelatin, wetting agent and ethanol that dries fast on the bleeding site to enhance hemostasis.” (sic) Even a cursory reading of Examples 2, 3, and 8 in which solvent was initially present will indicate to one of ordinary skill in the art that any solvent which was present during the preparation of the sponge was removed by drying before testing or potential use. Accordingly, the “drying enhancer” of Song would appear to be irrelevant to the claimed invention. Further Song does not appear to overcome the deficiencies of Yasushi with respect to a disclosure of a cross-linked gelatin sponge having an associated wetting agent that decreases hydration time of the gelatin sponge. Therefore, Yasushi in view of Song does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness as applied to either claim 22 or 43 and Applicant respectfully requests that the rejection of claim 22 and/or 43 be withdrawn.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

Accordingly, claims 23-33 and 42, which depend from nonobvious independent claim 22, and/or claims 45-47, which depend from nonobvious independent claim 43, also are believed to be nonobvious and Applicant respectfully requests that the rejections be withdrawn.

In the Response to Arguments, the Examiner appears to be responding to comments presented is a comment regarding the application of Yasushi to amended claim 22, now provisionally withdrawn. The single reference §103 rejection over Yasushi did not appear to consider all words in the claim in judging the patentability of that claim against the prior art and particularly did not appear to apply to claim 22 as amended in that paper. Applicant apparently did not convey the intent of the comment with sufficient clarity.

With respect to the “rejection” of claims 30, 32, and 33 over Yasushi in view of “US 6,603,061”, the Examiner appears to be referring to section 10 which is not in that portion of the Office Action presenting §103 rejections, said section ending with section 8 of the Office Action. It appeared to be a comment within the first of two sections labeled “Response to Arguments” rather than a claim rejection. Aside from incompletely identifying the reference [37 CFR 1.104, (d), (1)], it appears that the patent number provided is incorrect. It is believed that the intended reference may have been Wallace et al. (U.S. Patent No. 6,063,061). Although claims 22-33 and 42 are drawn to Invention I and Applicant has provisionally elected Invention II, corresponding to claims 43 and 45-47, subject to a request for reconsideration of the restriction requirement and assuming that the intended reference is indeed Wallace et al., it will be noted that the cited portions of the reference appear to disclose that gelatin and other materials may be hydrated without reference to hydration time or to the recited decreased hydration time of nonobvious independent claim 22 from which claims 30, 32, and 33 depend.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reconsideration and withdrawal of the rejections is respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Date: July 27, 2009



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